PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| (refrage | | | | |
|---|---|--|--|--|
| Applicant's or agent's file reference 2960/121WO | FOR FURTHER ACTION | See item 4 below | | |
| International application No. PCT/US2005/044008 | International filing date (day/month/year) 02 December 2005 (02.12.2005) | Priority date (day/month/year) 02 December 2004 (02.12.2004) | | |
| International Patent Classification (8t See relevant information in Form F | h edition unless older edition indicated) PCT/ISA/237 | - | | |
| Applicant CONFORMIS, INC. | | | | |

| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bits.1(a). | | | |
|----|---|---|--|--|
| 2. | This REPORT consists of a total of 7 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. | | | |
| 3. | This report contains indications relating to the following items: | | | |
| | Box No. I | Basis of the report | | |
| | Box No. II | Priority | | |
| | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | |
| | Box No. IV | Lack of unity of invention | | |
| | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | |
| | Box No. VI | Certain documents cited | | |
| | Box No. VII | Certain defects in the international application | | |
| | Box No. VIII | Certain observations on the international application | | |
| 4. | The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2). | | | |

| | Date of issuance of this report 05 June 2007 (05.06.2007) |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Beate Giffo-Schmitt |
| Facsimile No. +41 22 338 82 70 | e-mail: pt03.pct@wipo.int |

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)

(PCT Rule 44bis, 1(c))

Date of mailing (day/month/year) 14 June 2007 (14,06,2007)

Applicant's or agent's file reference 2960/121WO To:

SUNSTEIN, Bruce, D. Bromberg & Sunstein LLP 125 Summer Street Boston, MA 02110-1618 ETATS-UNIS D'AMERIQUE

DOCKETED

IMPORTANT NOTICE

International application No. PCT/US2005/044008

International filing date (day/month/year) 02 December 2005 (02.12.2005) Priority date (day/month/year) 02 December 2004 (02.12.2004)

Applicant

CONFORMIS, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

RECEIVED JUN 2 1 2007

BROMBERG & SUNSTEIN LLP

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

Beate Giffo-Schmitt

Facsimile No. +41 22 338 82 70

e-mail: pt03.pct@wipo.int

see form PCT//SA/220 R

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43*bis.*1)

| Date of mailing | |
|------------------|-------------------------------------|
| (day/month/year) | see form PCT/ISA/210 (second sheet) |

| Applicant's or agent's file reference see form PCT/ISA/220 | | FOR FURTHER ACTION See paragraph 2 below | |
|--|--|---|--|
| International application No. International filing date (PCT/US2005/044008 02.12.2005 | | layimonthiyear) | Priority date (day/monthlyear) 02.12.2004 |
| International Patent Classification (IPC) or both national classification and IPC INV. A61B17/17 A61B17/15 | | | |
| Applicant CONFORMIS, INC. | | | |

| 1. | This opinion | contains | indications | relating | to the | following | items |
|----|--------------|----------|-------------|----------|--------|-----------|-------|
| | | | | | | | |

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No, IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelly, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application
- 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendment, expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expirates later.

For further options, see Form PCT/ISA/220.

For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 Authorized Officer

Storer, J

Telephone No. +49 89 2399-7247



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2005/044008

| | Box N | o. I Basis of the opinion |
|----|--------|--|
| 1. | With r | agard to the language, this opinion has been established on the basis of the international application in guage in which it was filed, unless otherwise indicated under this item. |
| | la | nis opinion has been established on the basis of a translation from the original language into the following nguage , which is the language of a translation furnished for the purposes of international search nder Fulse 12.3 and 23.1(b). |
| 2. | With r | egard to any nucleotide and/or amino acid sequence disclosed in the international application and sary to the claimed invention, this opinion has been established on the basis of: |
| | a. typ | e of material: |
| | | a sequence listing |
| | | table(s) related to the sequence listing |
| | b. for | nat of material: |
| | | in written format |
| | | in computer readable form |
| | c. tim | e of filing/furnishing: |
| | | contained in the international application as filed. |
| | | filed together with the international application in computer readable form. |
| | | furnished subsequently to this Authority for the purposes of search. |
| 3. | h | n addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto- as been filled or furnished, the required statements that the information in the subsequent or additional opies is identical to that in the application as filed or does not go beyond the application as filed, as ppropriate, were furnished. |
| 4. | Addit | onal comments: |
| | | |
| _ | Box | No. II Priority |

- 1.

 The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
- 2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43b/s.1 and 64.1). Thus for the purposes of this opinion, the International filing date indicated above is considered to be the relevant date.
- 3. Additional observations, if necessary:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2005/044008

| Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | |
|---|---|-------|-----------------------------------|--|--|
| The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of: | | | | | |
| | the entire international application, | | | | |
| \boxtimes | claims Nos. 9-13 | | | | |
| because: | | | | | |
| | I the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): | | | | |
| | the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): | | | | |
| | the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. | | | | |
| × | no International search report has been established for the whole application or for said claims Nos. 9-13 | | | | |
| | the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: | | | | |
| | the written form | | has not been furnished | | |
| | | | does not comply with the standard | | |
| | the computer readable form | | has not been furnished | | |
| | | | does not comply with the standard | | |
| | 1 the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, d not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions. | | | | |
| | See separate sheet for further | detai | ils · | | |
| | | | | | |

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1-8

1. Statement

Novelty (N) Yes: Claims

No: Claims

Inventive step (IS) Yes: Claims

No: Claims 1-8

Industrial applicability (IA) Yes: Claims 1-8

No: Claims

Citations and explanations

see separate sheet

Re Item III.

In accordance with Rule 67.1(iv) PCT, claims 9-13 are exempted from international preliminary examination, since they describe methods of medical treatment. In particular, the method described in independent claim 9 includes the step of drilling an aperture into the surface of the patella, which is part of a method of treatment of a human or animal body by surgery and is therefore exempted from examination (see the PCT International Search and Preliminary Examination Guidelines, Ch. 9.08).

Re Item V.

- 1. Reference is made to the following documents:
 - D1: US 5 129 908 A (PETERSEN ET AL) 14 July 1992 (1992-07-14)
 - D2: US 5 885 298 A (HERRINGTON ET AL) 23 March 1999 (1999-03-23)
- 2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document) a drill-guide for engaging a surface of a patella, the drill guide comprising a mould (70, 80) having a first surface (128) that is configured to substantially match the surface of the patella (see column 6, line 38 to column 8, line 35, column 4, lines 50-64 and figures 1, 3 and 4).

Thus, document D1 discloses all of the technical features of claim 1. in addition, the aforementioned disclosure of document D1 anticipates the subject-matter of dependent claims 2-8.

The same result with respect to the lack of novelty of the subject-matter of claims 1-3 and 6 is obtained with document D2 (see column 4, lines 28-40, column 9, line 33 to column 10, line 9 and figure 3).

Therefore, the subject-matter of claims 1-8 is not novel (Art. 33(2) PCT) and as such these claims do not meet the criteria of Article 33(1) PCT.

- Claim 1 has not been delimited with respect to the closest prior art (document D1 or D2), which would have been appropriate (Rule 6.3(b) PCT).
- Reference signs have not been used throughout the claims, which would have been appropriate (Rule 6.2(b) PCT).
- The documents D1 and D2 should have been identified in the description and the background art disclosed therein briefly discussed (Rule 5.1(a)(ii) PCT).